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Remarks

Claims 1-6 and 8 - 18 are pending in the application. Claims 1 and 16 are amended. Claim 7 is canceled. Claims 17 and 18 are new. Claims 10 - 15 are withdrawn from consideration due to election/restriction.

Applicant wishes to notify the Examiner and the United States Patent & Trademark Office of a change in representation with respect to the prosecution of this Application. As indicated in the Kenyon & Kenyon letter dated August 22, 2006 from Gerard A. Messina to me, Kenyon & Kenyon is no longer my attorney(s) in this Application. I have not retained any other representation at this time.

Please ensure that all further correspondence is directed to me.

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Claim Rejections 35 USC §112

Claims 1-7 and 16 have been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant respectfully traverses this rejection.

As per the Examiner's comments, Claims 1 and 16 are amended herein. Also, claim 7 is canceled. Claims 2-6 have been rejected based merely on their dependency from claim 1.

In view of the amendments to claims 1 and 16 and cancellation of claim 7, Applicant respectfully requests reconsideration and removal of the rejection of claims 1-6 and 16.

Claim Rejections 35 USC §103

Claims 1, and 3 - 7: Lee et al. (5828776)

Claims 1 and 3 - 7 have been rejected under 35 USC § 103 as being unpatentable over Lee et al. ("Lee") (5828776). Applicant respectfully traverses this rejection.

Lee appears to teach an apparatus and method for biological tissue classification applicable to pap smear diagnostic testing. The apparatus is equipped with a microscope and processor to acquire and digitize images from slides. The cells which are also called objects, in the images are classified using a single cell classifier 24, group classifier 26, a thick group classifier 38 and a FOV integrator 30. Each classifier performs an independent analysis of the tissue.

The single cell classifier 24 classifies the free lying and non-nuclear overlapping cells. These cells are detected and a value from 0-1 is assigned to each cell. A value of 0 is assigned to normal cells and a value of 1 is assigned to malignant cells. Lee calls the value a confidence value. The cells given a confidence value below a normal threshold are termed negative and those cells with a confidence value greater than the threshold are alarmed cells. The group classifier 26 and thick group classifier 28 also generate outcomes of potential normal and abnormal groups or objects. See Lee Col. 5, line 16 – Col. 6 line 10.

The FOV integrator 30 processes the results of the classifiers. In cases with inconsistent results, reclassification of the object occurs. See Col. 6, line 11 – Col. 7 line 65. The final reclassification results are saved and the FOV integrator 30 uses the data from the reclassification steps for slide classification.

Just because Lee uses the term "confidence value" with respect to classifying a biological tissue sample, does not mean that Lee teaches or renders obvious all the features recited in

Applicant's claims. For example, Lee does not teach or render, "A method for determining an overall level of confidence for a medical clinical conclusion comprising . . . c. determining an overall level of confidence parameter as a function of each confidence parameter and associated impact value. ," as recited in claim 1. Rather, Lee is limited to a method and apparatus for classifying pap smear as normal or abnormal.

The Examiner admits that Lee fails to teach the features of claim 1 recited above. See Office Action page 3 lines 19-26. To make up for this deficiency the Examiner contends that one of ordinary skill in the art would perform the recited calculation based on the teachings of Lee in column 19, lines 5-8 and 47-48 and column 20, lines 23-36. Column 19, lines 5-8 recites, "However, those skilled in the art will appreciate that confidence values may be compared, combined or used in various ways to classify the objects as normal, abnormal or artifacts." Also, Column 20, lines 23-25 recite, "It will be apparent to those skilled in the art that the classification data may be combined in a number of ways to determine the overall rating for the slide."

Applicant respectfully submits that no portion of Lee including those cited by the Examiner would render it obvious to one of ordinary skill in the art to determine an overall level of confidence as recited in Claim 1. Each of the portions of Lee cited by the Examiner appear to discuss varying combinations of confidence values and classification data to classify objects as normal, abnormal or artifacts and/or determine an overall rating for a slide. This does not teach or render obvious the features of claim 1 because determining an overall rating of a slide is not the same as determining and overall confidence parameter as recited in claim 1. An overall rating of a slide refers to whether or not the slide the slide is normal or abnormal. Lee seems to suggest that the accuracy of the overall rating of the slide may be improved by varying

calculations of confidence values and classification data. However, Lee does not teach, suggest or provide any information that would render it obvious to one of ordinary skill in the art to "determining an overall level of confidence parameter as a function of each confidence parameter and associated impact value." as recited in claim 1.

Taking steps to improve the accuracy of a medical conclusion such as whether a slide contains normal or abnormal cells is not the same as determining the overall level of confidence of the conclusion of normalcy or abnormality. Further, nothing in Lee renders it obvious to one having ordinary skill in the art to determine the overall level of confidence of a medical conclusion or even how this would be done. Rather, Lee contends that it offers an improvement in the accuracy of the art of classifying tissue samples. Therefore, Lee does not render obvious a need to determine the overall confidence of its assessment of the pap smear.

Claims 3 - 6 are dependent upon claim 1. As discussed above, Lee does not teach or render obvious the features of claim 1. Therefore, Lee, also, does not teach the features of dependent claims 3 - 6. Claim 7 is canceled herein.

Accordingly, Applicant respectfully requests removal of the rejection of claims 1 and 3 - 6.

Claims 2: Lee et al. (5828776) and Friedman (6055494)

Claim 2 has been rejected under 35 USC § 103 as being unpatentable over Lee et al. (5828776) as applied to claim 1 and further in view of Friedman (6055494). Applicant respectfully traverses this rejection.

Even if it would possibly be obvious to one of ordinary skill in the art to combine Lee and Friedman, which Applicant does not admit, the references either alone or in combination would not teach all the features of claim 2. As discussed above, Lee does not teach or render

obvious all the features of claim 1 from which claim 2 depends. Friedman merely discloses a system and method for medical language extraction encoding, and does not make up for the deficiencies of Lee.

Accordingly, Applicant respectfully requests removal of this rejection with respect to claim2.

Claim Rejections 35 USC §102

Claims 8, 9 and 16: Lapointe et al. (2003:0105731)

Claims 8, 9 and 16 have been rejected under 35 USC §102(b) as being anticipated by Lapointe et al. ("Lapointe") (2003:0105731). Applicant respectfully traverses this rejection.

Lapointe has been improperly applied as prior art under 35 USC §102(b) in the rejection Applicant's invention. 35 USC §102(b) states

> A person shall be untitled to a patent unless- . . . (b) the invention was patented or described in a printed publication in this . . . more than *one year prior* to the date of the application for a patent in the United States . . . . (emphasis added)

Under §102(b), prior art must have a publication date greater than a year before Applicant's filing date.

Applicant's Application No. 09/814,646 has a filing date of is March 23, 2001with a claim of priority of two earlier provisional applications nos. 60/191,524 filed on March 23, 2000 and 60/191,967 filed on March 24, 2000. However, Lapointe was not published until June 5, 2003. Since Lapointe was published after March 23 and 24, 2000, it does not meet the time requirements of §102(b) and does not qualify as prior art under §102(b).

Accordingly, Applicant respectfully requests removal of this rejection and allowance of claims 8, 9 and 16.

Applicant notes that even if Lapointe could qualify as prior art under a different standard of 35 USC §102, Lapointe would not teach claims 8, 9 and/or 16. Lapointe discloses methods of training and using neural networks in the medical field for uses such as to assess risks of pregnancy related disorders and to validate biochemical testing. To perform each assessment, Lapoint discusses that is it necessary to train and develop a particular neural network system for each use. In particular, the neural networks trained to assess the risk for preterm pregnancy are different than those used to validate biochemical tests because different variables are required.

Lapointe discusses training a neural network system for building or validating a biochemical diagnostic test using the Enzyme Linked Immunosorbent Assay or ELISA test. See page 12 paragraph [0129]. The development of an effective diagnostic test requires the use of a Western Blot for the suspected disease. The neural network learns which areas of the Western Blot are important for the suspected disease. Then, the ELISA test is performed for only these areas.

To assess the risk of preterm pregnancy, Lapointe discusses using many data points such as patient history, clinical information and the fetal fibronectin (fFN) test, but does not include the Western Blot. The preterm pregnancy neural networks learn to use a specific set of data in a manner unique to the assessment of preterm pregnancy.

Although Lapointe claims to perform some sort of assessment of medical data, Lapointe does not teach "A method for determining an overall level of confidence for medical clinical conclusion," as recited by claims 8 and 9 and/or, "A method for determining an overall level of confidence for a conclusion," as recited by claim 16. Assessing the risk of a preterm pregnancy

and validating a biochemical diagnostic test are examples of generating new clinical data or conclusions rather than determining an overall level of confidence of a conclusion. For example, Lapointe claims to generate more accurate clinical data regarding the risk of a preterm pregnancy, it does not propose analyzing a preterm pregnancy risk assessment and patient data to determine the "overall level of confidence" of a preterm pregnancy risk assessment. Rather, Lapointe merely provides statistics supposedly indicating that the neural network approach will improve the accuracy of the risk assessment.

Simply stated, generating new data and new methods of generating data does not teach "determining an overall level of confidence for a conclusion" or data. An overall confidence level can be determined for all data whether or not it is medical/clinical, new or claims to be more accurate then previous data or is in the form of a percentage. For example, if the preterm pregnancy risk is assessed at 65%, an overall level of confidence in the value of 65% can be determined.

Accordingly, Lapointe fails to disclose the features of claims 8, 9 and 10. Therefore, Applicant respectfully requests reconsideration and withdrawal of this rejection.

New Claims

Claims 17 and 18 are newly added. These claims are supported by the Specification by at least paragraph [0009].

Applicant respectfully submits that each of claims 17 and 18 contain allowable subject matter. As discussed above, none of the references cited in the Office Action as a basis for the 35 USC §§102(b) and 103(a) rejections teach or render obvious the feature of "determining an overall level of confidence for a medical conclusion." Therefore, the references fail to teach "A system for determining an overall level of confidence for a medical conclusion," as recited by

claim 17. Claim 18 depends from claim 17 and is allowable at least based on its dependency from claim 17.

Conclusion

In view of the above discussions, it is respectfully submitted that each of claims 1-6 and 8, 9 and 16 – 18 contain allowable subject matter. A notice of allowance to this effect is requested. In the alternative, continued prosecution is requested.

Thank you very much for considering the above comments. Any assistance that you can provide in the prosecution of my patent application is greatly appreciated. If you have any questions or need any further assistance or clarification, please do not hesitate to contact the undersigned at (856)313-6630 or (215)629-1045.

September 1, 2006

Scott H. Jaeger M.D.
Applicant/Inventor

Application No. 09/815,646
Art Unit 3626

Attachment A: Letter from Kenyon & Kenyon

KENYON & KENYON LLP
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August 22, 2006

VIA COURIER
Scott H. Jaeger, M.D.
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Re: U.S. Serial No. 09/815,646
METHOD AND SYSTEM FOR CLINICAL KNOWLEDGE MANAGEMENT
Our Ref.: 11506/3

Dear Dr. Jaeger:

Further to your recent letter, we enclose our file for the above-identified application. As reported to you in our April 4, 2006 letter, there remains an outstanding office action for this application. Please note that if no response is filed by the **September 3, 2006** final deadline, this application will become abandoned for non-responsiveness.

In accordance with your instructions, we return responsibility for this application to you and will do no further work on this case.

Kindly acknowledge your receipt of this letter and the enclosures by facsimile to 212-425-5288.

Very truly yours,

Gerard A. Messina

Enclosures

cc: Michael P. Paul, Esq. (w/o encls.)